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de Pabellones Quirúrgicos y Esterilización**



Implementation of a complementary monitoring tool for high-level disinfection (HLD) of endoscopic devices

Troy Ejsmentewicz¹, Gerthy Rios-Rioseco², Francisca Asis², Karen Saldivia²,
Celia Podesta-Medina³ and Franz Villarroel-Espíndola¹.

¹Traslational Medicine unit, ²Sterilization unit, ³Endoscopy unit, Instituto
Oncológico Fundación Arturo López Pérez. Santiago, Chile.

E-mail: troy.ejsmentewicz@falp.org

Translational Research at FALP

Since 2019, the direct path between a discovery and its applicability

Founded by Arturo Lopez Perez's widow in 1954.
FALP is a non-profit private Cancer Centre

In a regular year:
125,000 medical consultations
21,000 new patients
6,500 surgeries
19,100 Chemotherapies
37,000 Therapeutic doses
1,200 Radiotherapies
>40 clinical trials
Prevention:
>900,000 insured
24,000 mammography

Translational Medicine Laboratory at FALP is a unit for Research and Innovation.

Mission

To be the link between experimentation and clinical applicability to transfer benefits and opportunities to the patient, the clinician and the scientific researcher.



Gene expression and Sequencing



Preclinical studies

Molecular pathology



The problem' size

USA in 2019

Total endoscopic procedures: 22,162,641

Colonoscopy: 13,837,748

Upper endoscopy: 7,459,419

Others: 865,474

(Peery AF, et al. *Gastroenterol*, 2021)

Composite infection rate

Non-ERCP upper endoscopy

0.123% (1083 out of 876,263 procedures) from 16 studies

Lower endoscopy

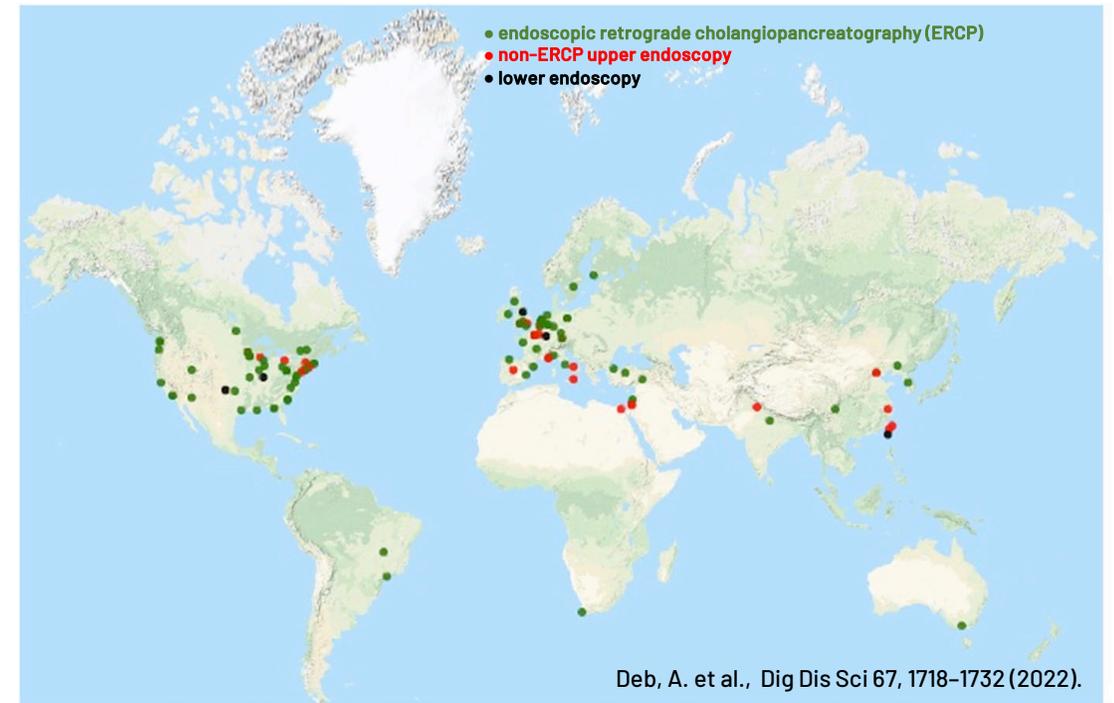
0.073% (1081 out of 1,488,779 procedures) from 3 studies

(Deb A, et al., *Dig Dis Sci*, 2022 -systematic review-)

FALP. Average per month 2023,

486 endoscopic procedures

512 reprocessed devices

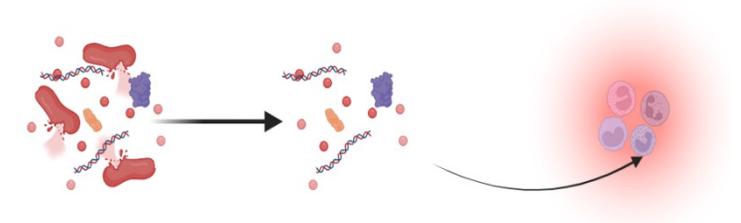


Worldwide distribution of endoscopy-associated infection reported between 2011-2020.

High-level disinfection (HLD) quality control

Any HLD procedure for reused devices must generally comply with (FDA recommendation):

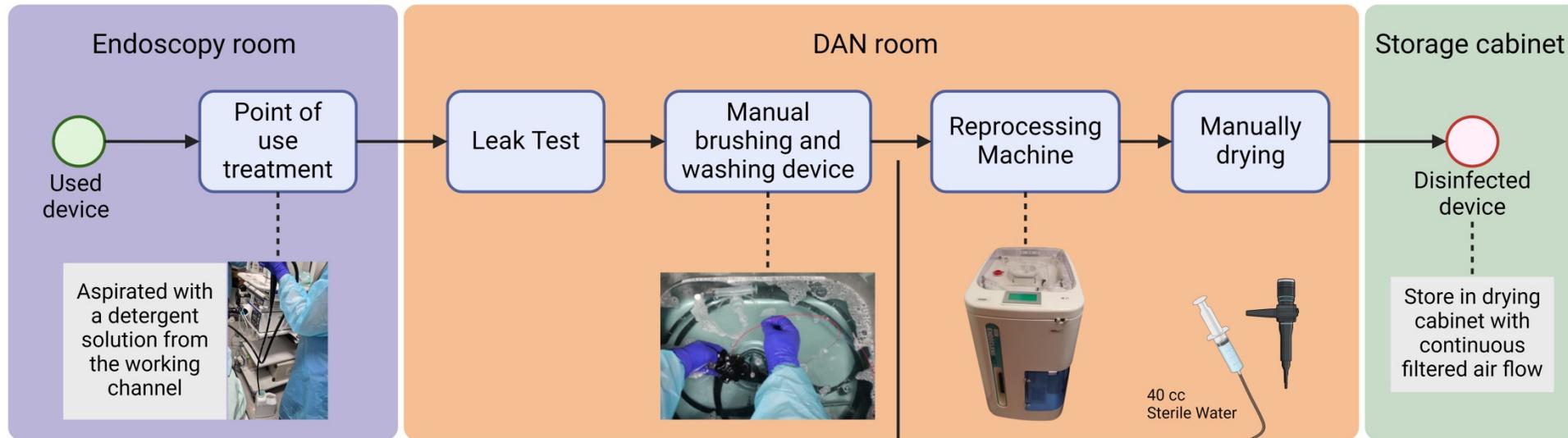
- Less than 1 colony-forming unit (CFU) for high-concern microorganisms: such as *Staphylococcus aureus*, *Enterococcus spp.*, *Streptococcus sp.*, *Viridians group*, *Pseudomona auroginosa*, *Klebsiella spp.*, *Salmonella spp.*, *Shigella spp.*, and other Gram-negative enteric bacilli.
- up to 10 CFU, for low-concern bacteria, such as coagulase-negative *Staphylococcus, micrococci, Diptheroides, Bacillus spp.*, and other spherical Gram-positives.



However, the absence of microbiological growth does NOT rule out the presence of biological remnants, such as lipid membrane, DNA, proteins, endotoxins and other molecules with a **potential pro-inflammatory activity**.



Verification of a correct HLD procedure



Standard workflow for HLD at Fundación Arturo López Pérez FALP-Cancer Centre.

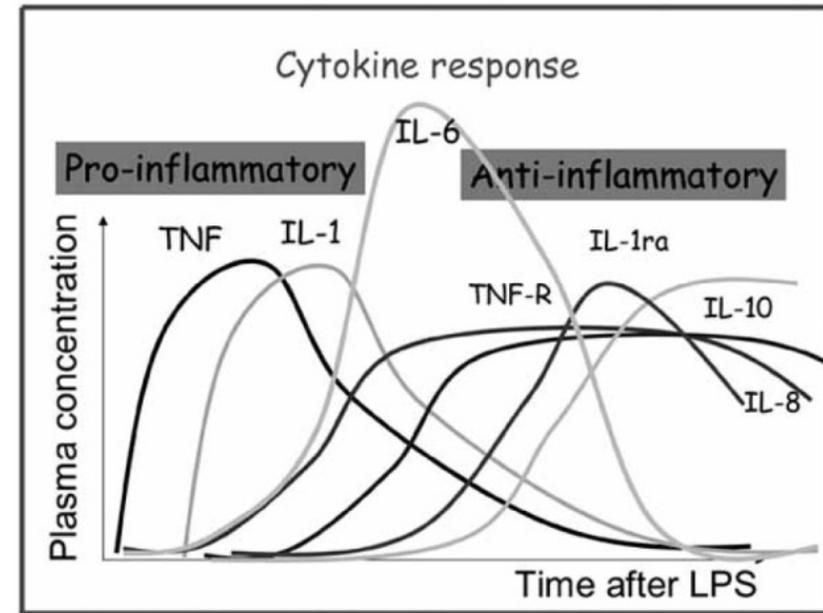
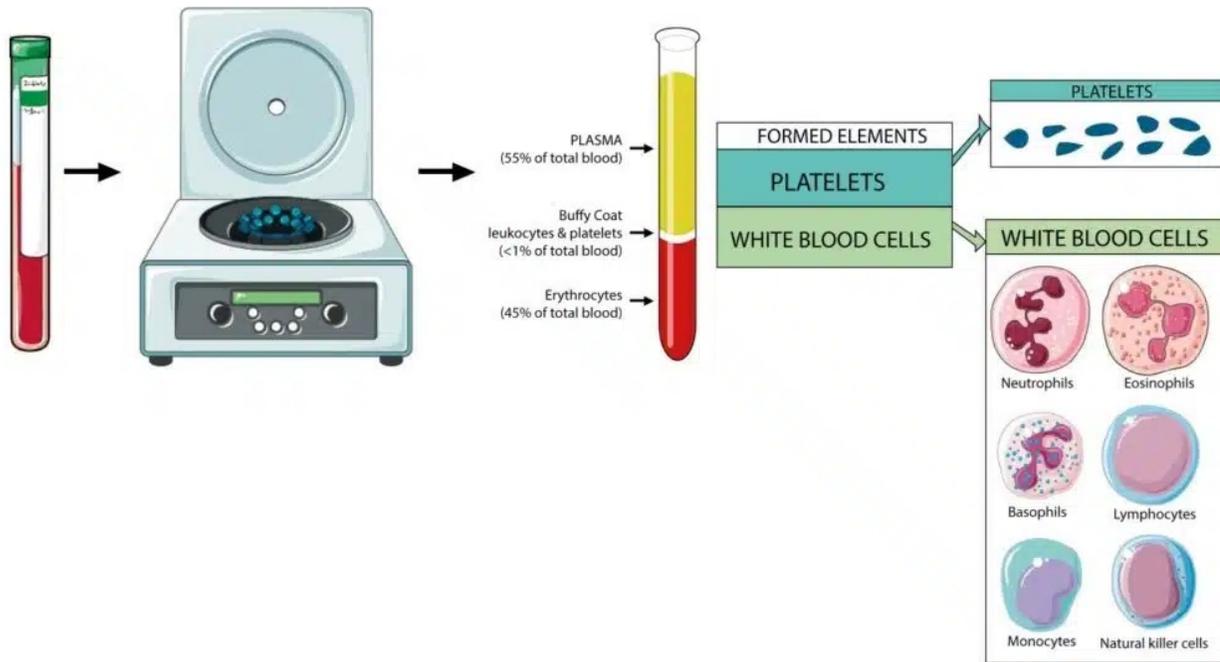
ATP bioluminescence assay is frequently used as quality control

Is this assay the right control?

Can we evaluate the presence of a pro-inflammatory molecule?



Biological sensors for *in vitro* assays



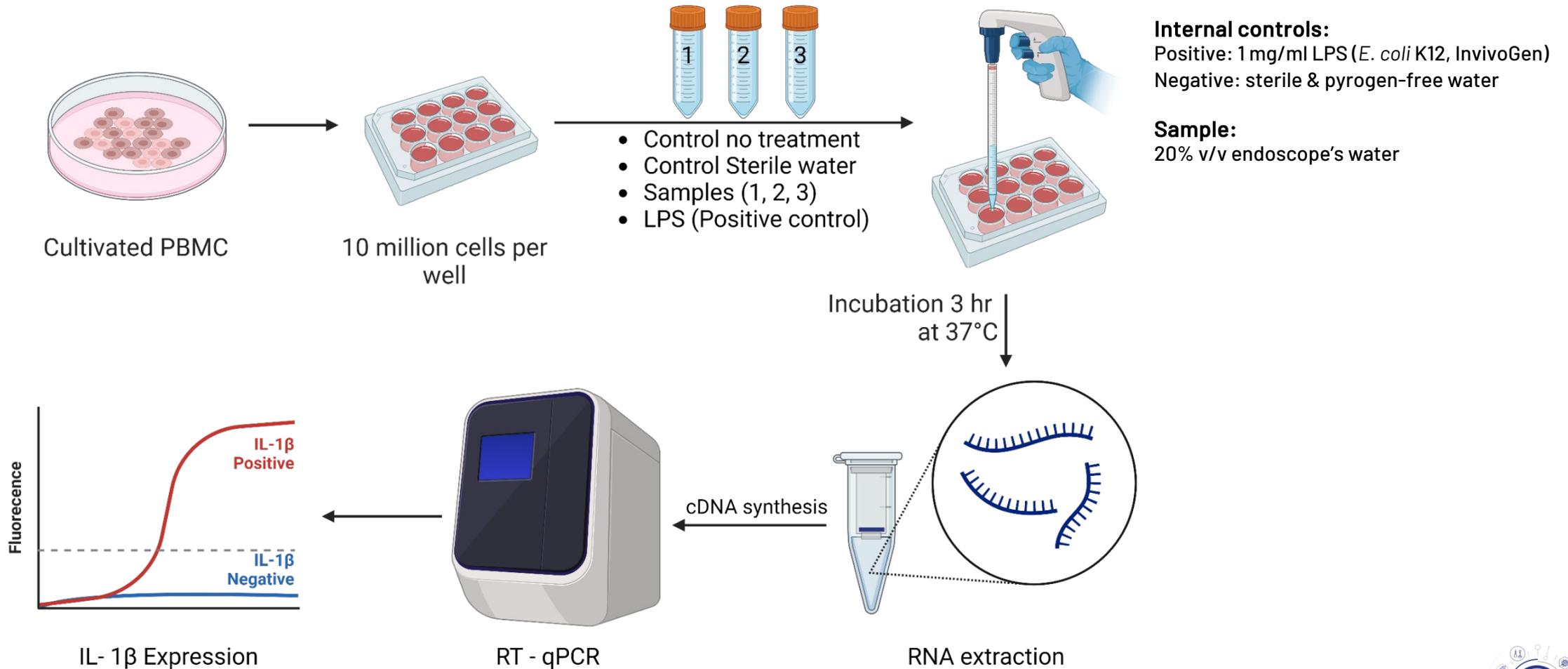
Andreasen, A. S., (2008). *Current medicinal chemistry*, 15(17), 1697-1705.

FALP Translational Medicine Laboratory has the capacity to perform cell cultures of immune cells to perform *in vitro* assays.

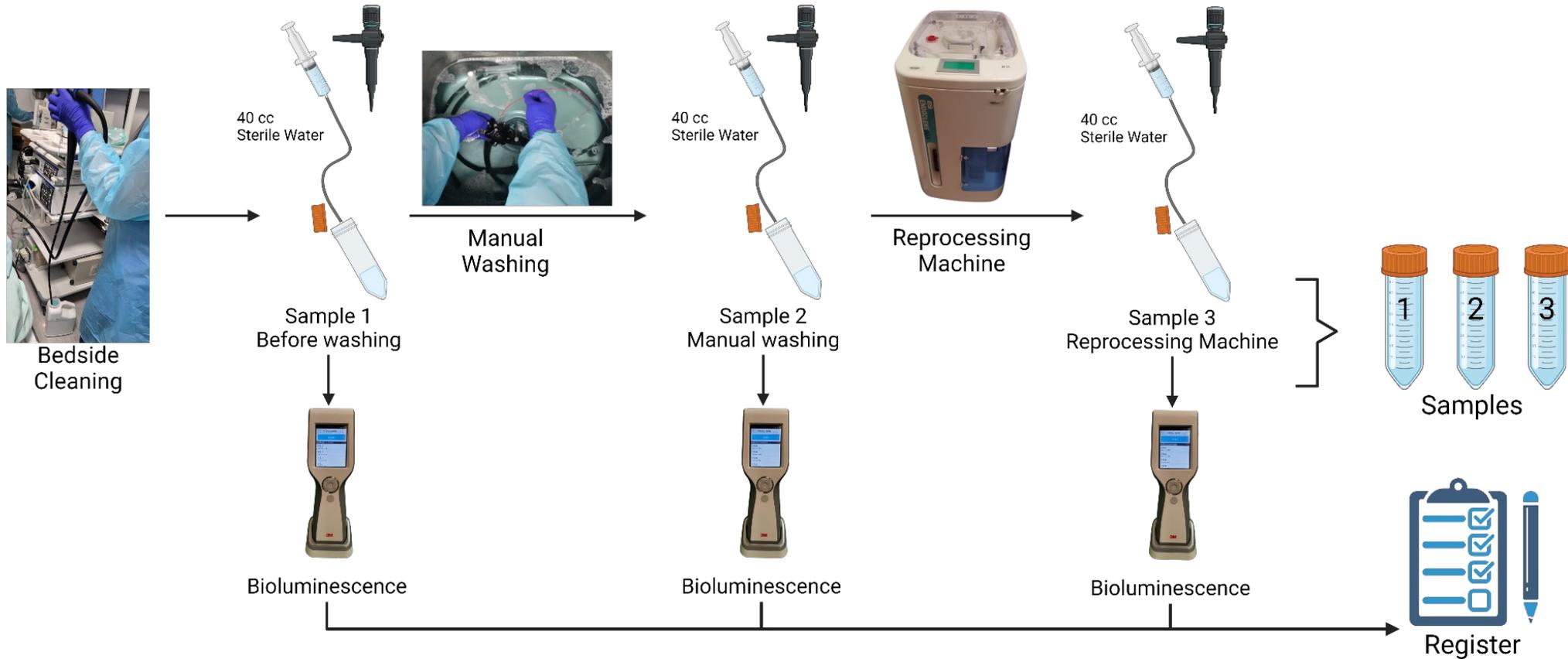
González-Stegmaier, R., et al., *Molecules* 2023, 28(5), 2394.



In-house protocol to evaluate HLD's performance



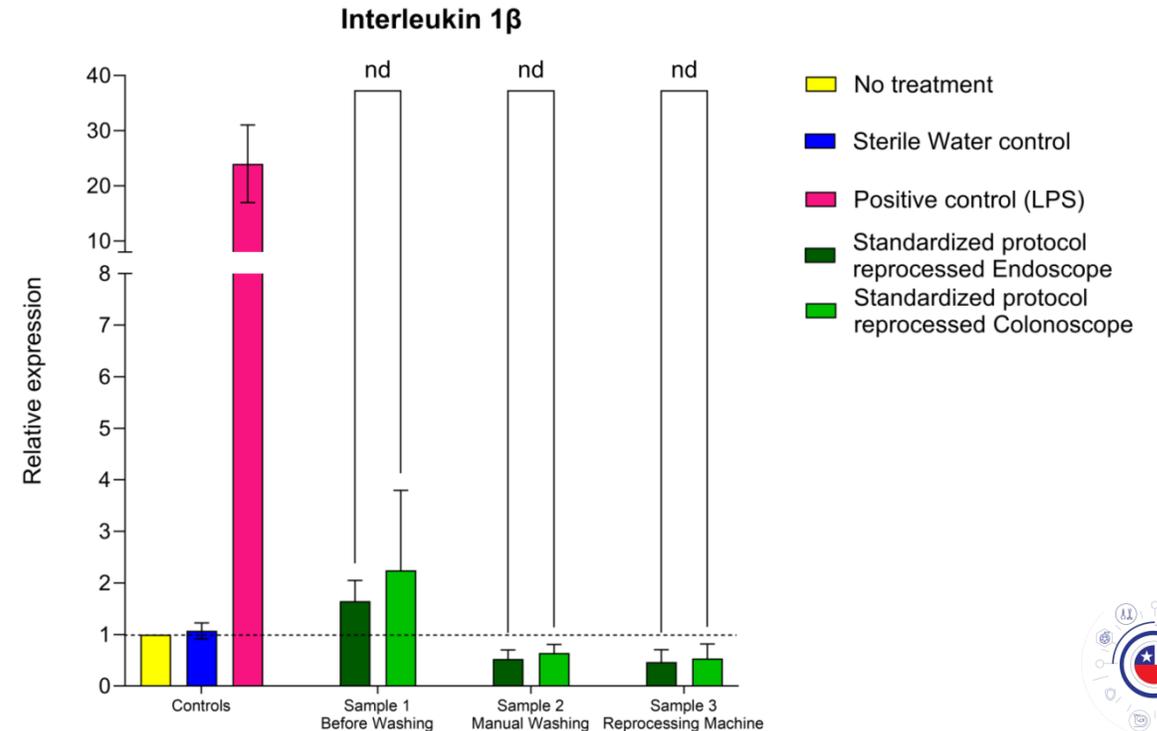
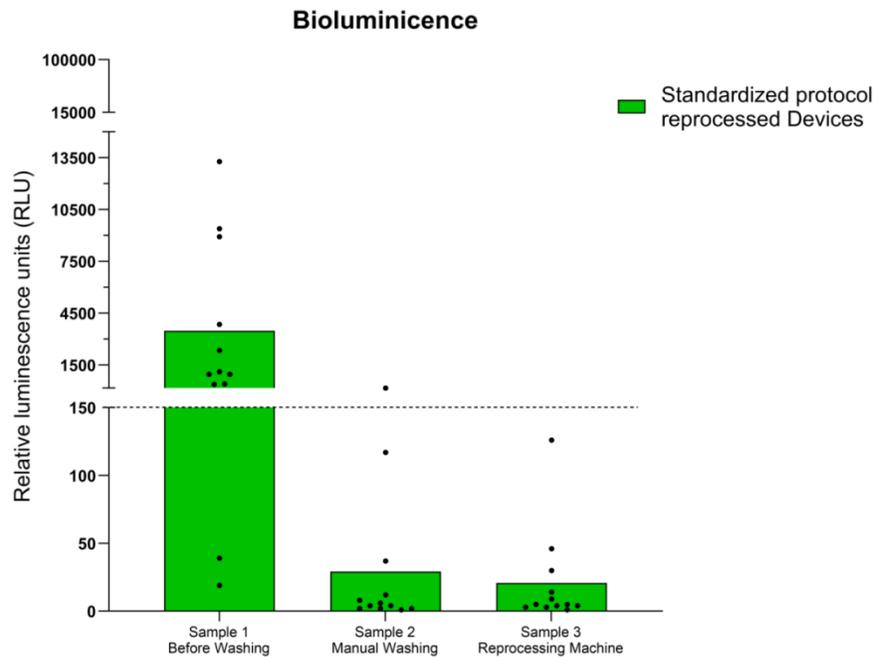
Sampling design



Schematic representation of sampling collection. Wash water is collected from the working channel of each device at three steps. ATP levels is tested by bioluminescence as an indicator of cleanliness. 36 devices (IC 90%, 5% error) were evaluated before and after manual washing, and after an automatic reprocessing machine

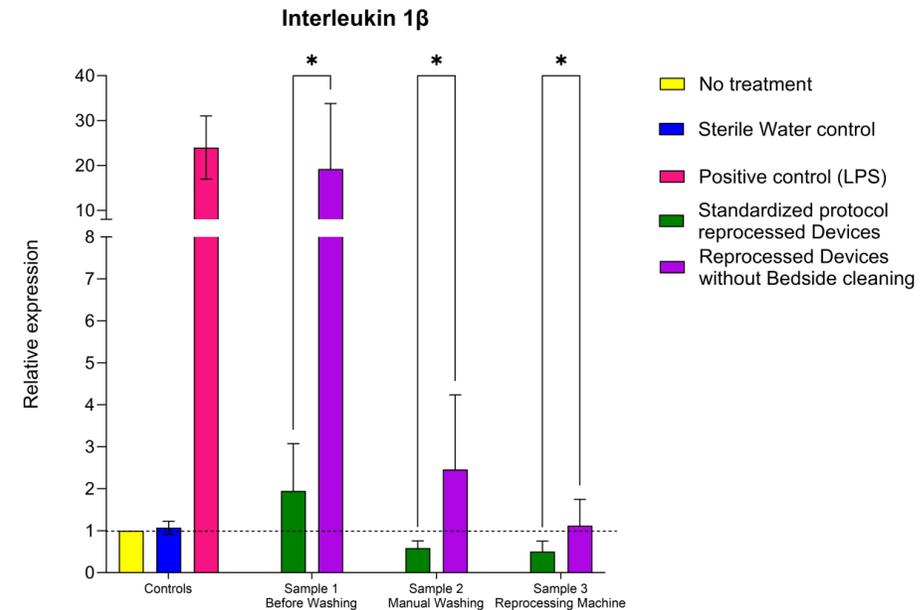
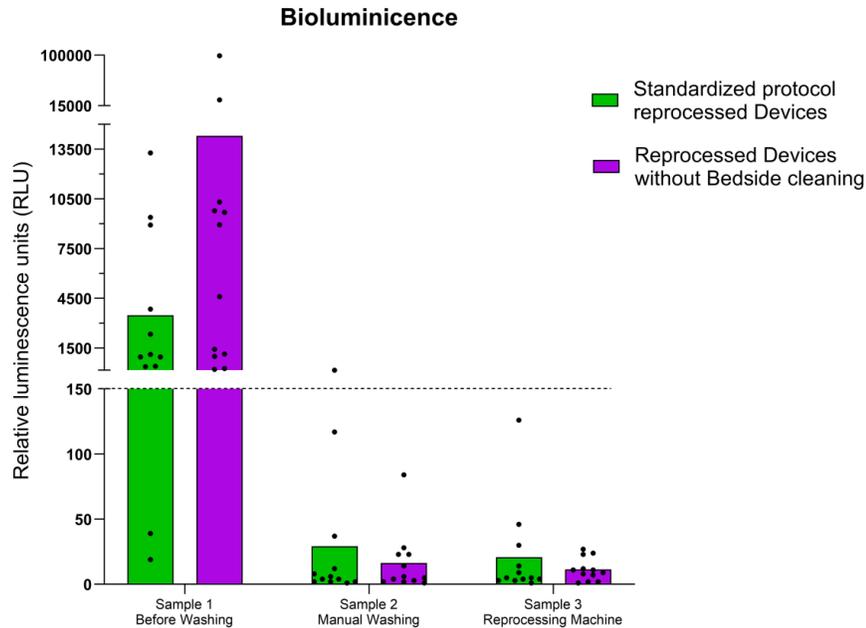


standardize HLD protocol



Modified HDL protocol N°1

absence of detergent during aspiration at point of use



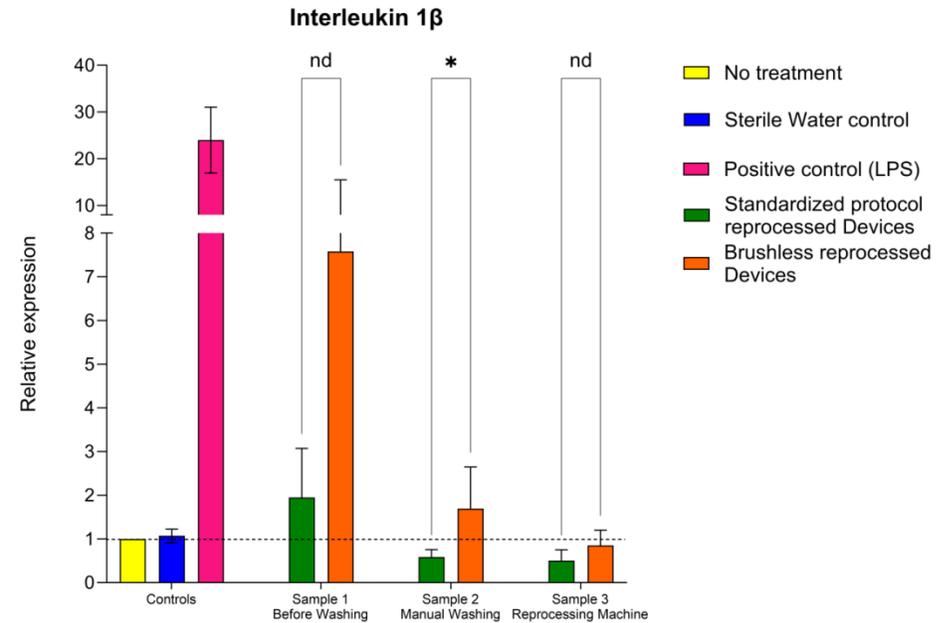
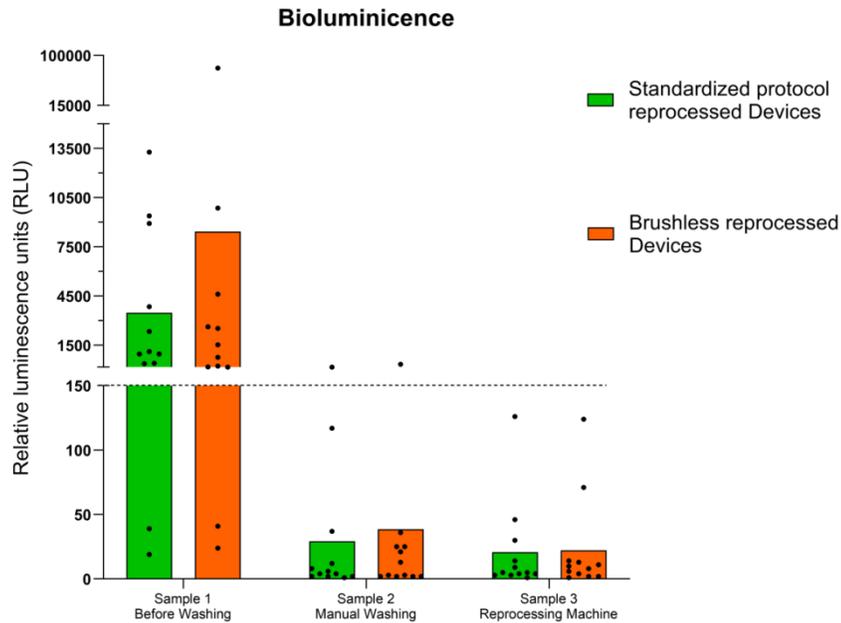
Remarks

- Importance of bedside cleaning.



Modified HDL protocol N^o2

Absence of brushing in the HDL room



Remarks

- Importance of brushing endoscope and using a reprocessing machine



CONCLUSIONS

- We developed an in-house method based on the biological response of live cells to evaluate the efficiency of high-level disinfection (HLD) protocols used for reprocessing endoscopes.
- Based on our biological test, the standardized HLD protocol for devices used for colonoscopy or endoscopy at FALP is robust enough to eliminate any inflammatory component.
- Disruptions in the standardized HLD protocol, such as the lack of detergent during the aspiration step at the point-of-use or the absence of brushing during the manual washing, significantly increases the presence of residuary inflammatory molecules.
- ATP detection by bioluminescence is an indicator of cleanliness but it does not correlate with inflammatory activity and IL-1 β mRNA levels.



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TO ALL OUR PARTICIPANTS, PATIENTS AND THEIR FAMILIES

